

REMARKS

This responds to the Office Action mailed on December 1, 2003.

Claims 1, 17, and 31 are amended. No claims are canceled or added. As a result, claims 1, 3-17 and 19-35 remain pending in this application.

A detailed response to the rejections follows. However, Applicant reserves all applicable rights not exercised in connection with this response, including, for example, the right to swear behind one or more of the cited references, the right to rebut any tacit or explicit characterization of the references, and the right to rebut any asserted motivation for combination. Applicant makes no admission regarding the prior art status of the cited references.

Request For Telephonic Interview

Applicant's representative, Suneel Arora, respectfully requests a telephonic interview at the Examiner's convenience to discuss the presently pending claims, including the claim amendments made herein, with respect to the present rejection under § 102 by Sheldon et al. (U.S. Patent No. 6,044,297) and under § 103 using Sheldon et al., Combs et al. (U.S. Patent No. 5,957,861), Ferek-Petric et al. (U.S. Patent No. 5,913,879), Strandberg (EP 0 620 420 A1), and Alt (U.S. Patent No. 5,354,317). Applicant would like the opportunity to compare detecting hypotension using a thoracic impedance that indicates a net fluid shift away from the thorax with references that detect pulmonary edema. Applicant would also like the opportunity to compare adjusting a "rate response factor" in response to hypotension with references that merely adjust a pacing rate in response to a change in posture.

§102 Rejection of the Claims

Claims 31, 33 and 35 were rejected under 35 U.S.C. § 102(b) for anticipation by Sheldon et al. (U.S. Patent No. 6,044,297). Applicant respectfully traverses. Applicant has amended claim 31 to overcome this basis of rejection of these claims. Applicant respectfully submits that claim 31, as amended, is fully supported by the present patent specification, such as at page 8, lines 8 -16, and at page 9, line 17 through page 10, line 10 of the present patent application.

Applicant cannot find any disclosure in Sheldon et al. of a means for detecting a hypotension in a subject and providing a responsive hypotension detection indicator in response to at least one of a thoracic-impedance indicated fluid shift away from the thorax and an acceleration-indicated change in activity level from resting to active, as presently recited or incorporated in these claims. The cited portions of Sheldon et al. apparently disclose using accelerometers to determine a change in posture, instead of either determining hypotension using transthoracic impedance, or determining hypotension using a change in activity from resting to active. For example, Sheldon et al. describes switching from a pacing rate of 50 pulses per minute when the patient is sitting to 70 pulses per minute when the patient is standing. (*See* Sheldon et al. at column 7, lines 23-26.) By contrast, claim 1 presently recites indicating hypotension when thoracic impedance indicates a fluid shift away from the thorax (without needing any change in posture) or when an accelerometer indicates that the subject has shifted from resting to active (again, without needing any change in posture).

Also, Applicant cannot find any disclosure in Sheldon et al. of changing a “rate response factor” in response to a detected hypotension. A rate-responsive cardiac rhythm management devices paces at an indicated pacing rate that is some function of a sensor-indicated metabolic need, as illustrated by way of example in FIG. 3 of the present patent application. The present claims clearly recite that the “rate responsive factor” relates a component of a patient activity or respiration metabolic need sensor signal to such a sensor-indicated pacing rate. For example, in FIG. 3, the “rate response factor” is a slope of the function mapping the sensor signal to the sensor-indicated pacing rate. Sheldon et al. does not disclose adjusting such a slope or other “rate response factor” relating a component of a patient activity or patient respiration metabolic need sensor signal to a sensor-indicated pacing rate. Instead, Sheldon et al. apparently merely steps up pacing from 50, when a patient is sitting, to 70 when the patient stands up, without regard as to the patient’s activity level or respiration level. (*See* Sheldon et al. at column 7, lines 23 – 26.)

Because Sheldon et al. does not disclose all elements presently recited in claims 31, 33 and 35, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

1. Claims 32 and 34 were rejected under 35 USC § 103(a) for obviousness over Sheldon et al. (U.S. Patent No. 6,044,297) in view of Combs et al. (U.S. Patent No. 5,957,861). Applicant respectfully traverses.

Applicant cannot find in the cited portions of Sheldon et al. and/or Combs et al. any disclosure, teaching, or suggestion of a means for detecting hypotension in a subject and providing a responsive hypotension detection indicator in response to at least one of a thoracic-impedance indicated fluid shift away from the thorax and an acceleration-indicated change in activity level from resting to active, as presently incorporated in these claims. As discussed above, the cited portions of Sheldon et al. disclose only a posture detector, rather than a “thoracic-impedance indicated fluid shift away from the thorax” or an “acceleration-indicated change in activity level from resting to active.” Moreover, Combs et al. uses transthoracic impedance to detect pulmonary edema, rather than a fluid shift away from the thorax.

In Applicant’s previous response, Applicant submitted the following remarks to distinguish edema from hypotension:

Applicant would like to strongly emphasize that Combs et al. does not relate to hypotension. Instead, Combs et al. apparently pertains to discerning edema. (*See* Combs et al. at Abstract). Moreover, Combs et al. states that pulmonary edema refers to fluid accumulation in the lungs, which involves a fluid shift toward the thorax. (*See, e.g.,* Combs et al. at column 1, lines 27-36.). By contrast, the present claims refer to hypotension, as detected using thoracic impedance to detect a fluid shift away from the thorax. Similarly, the specification of the present patent application notes that hypotension refers to “low blood pressure” or “too-low intravascular fluid tension,” which is associated with a fluid shift away from the thorax. (*See* Application at page 2, lines 25-26; *see also* page 8, line 28, *see also* page 9, lines 1-16.) As explained in Combs et al, edema—in direct contrast to hypotension—involves fluid accumulation in the lungs, that is, a fluid shift toward the thorax. Therefore, Combs et al.’s discerning edema fails to disclose (and actually teaches directly away from) detecting hypotension. Therefore, because all elements of the present claims are not disclosed, taught, or suggested in Sheldon et al. and/or Combs et al, and because Combs et al. furthermore actually teaches away from the present claim language, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims.

(See October 15, 2003 Amendment and Response at 11.) The present Final Office Action, however, failed to respond to these remarks. Therefore, Applicant is left unable to understand how Combs et al.'s detecting of edema constitutes the claimed hypotension detection indicator that operates in response to a thoracic-impedance indicated fluid shift away from the thorax.

In fact, the rejection has acknowledged that edema is manifested by increased water contained in the lungs. (See Final Office Action at 3 and 6.) However, how does such water accumulated and contained within the lungs somehow leave the lungs and shift away from the thorax? Applicant can find absolutely no disclosure of this in Combs et al. To the extent that the shifting away from the thorax of water accumulated and contained within the lungs is notoriously well known in the art, Applicant respectfully objects such reliance on Official Notice, and respectfully requests that the Examiner provide a reference to support such an assertion. See MPEP Section 2144.03.

Applicant respectfully notes that a standard medical dictionary appears to take exactly the opposite position, defining pulmonary edema as

diffuse *extravascular* accumulation of fluid in the pulmonary tissues and air spaces due to changes in hydrostatic forces in the capillaries or to increased capillary permeability; it is marked by intense dyspnea.

(See Dorland's Pocket Medical Dictionary, 25th ed. at 269 (emphasis added). Because pulmonary edema causes fluid to accumulate *outside* the blood vessels in pulmonary tissues and air spaces, Applicant is simply unable to understand exactly how the rejection can take the position that such accumulated *extravascular* interstitial fluid from pulmonary edema will somehow leave the lungs and shift away from the thorax toward the extremities. Again, Applicant respectfully requests a reference for any such assertion. Because Combs et al., which relates to edema, apparently pertains only to water accumulated and contained within the lungs, Applicant respectfully submits that it does not disclose—and actually teaches away from—using a fluid shift away from the thorax.

Also, as discussed above, Applicant cannot find any disclosure in Sheldon et al. and/or Combs et al. of changing a “rate response factor” in response to a detected hypotension. A rate-responsive cardiac rhythm management devices paces at an indicated pacing rate that is some function of an activity or respiration sensor-indicated metabolic need, as illustrated by way of

example in FIG. 3 of the present patent application. The present claims clearly recite that the “rate responsive factor” is such that it relates a component of a patient activity or patient respiration metabolic need sensor signal to such a sensor-indicated pacing rate. For example, in FIG. 3, the “rate response factor” is a slope of the function mapping the activity or respiration sensor signal to the sensor-indicated pacing rate. Sheldon et al. does not disclose adjusting such a slope or other “rate response factor” relating a component of a patient activity or respiration metabolic need sensor signal to a sensor-indicated pacing rate. Instead, Sheldon et al. apparently merely steps up pacing from 50, when a patient is sitting, to 70 when the patient stands up. (See Sheldon et al. at column 7, lines 23 – 26.)

Applicant respectfully submits that because all elements of claims 32 and 34 are not disclosed, taught, or suggested in Sheldon et al. and/or Combs et al., no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

2. Claims 1, 3-8, 10, 13, 17, 19-25 and 27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ferek-Petric et al. (U.S. Patent No. 5,913,879) in view of Strandberg (EP 0 620 420 A1) and further in view of Combs et al. (U.S. Patent No. 5,957,861). Applicant respectfully traverses.

Concerning claims 1, 3-8, 10, and 13:

Applicant has amended claim 1 to overcome this rejection of claim 1 and its dependent claims. Claim 1 presently recites detecting a condition correlative to hypotension including detecting a thoracic impedance signal associated with a portion of the subject’s thorax that includes a plurality of blood vessels, in which the detecting the thoracic impedance signal includes detecting a component of the thoracic impedance associated with a net fluid shift away from the thorax. (See Application at page 7, line 14 – page 9, line 6.) Applicant can find no such disclosure, teaching, or suggestion in the cited portions of Ferek-Petric et al. and/or Strandberg and/or Combs et al. For example, instead of detecting impedance against a substantial portion of the thorax that includes multiple vessels for obtaining an indication of net fluid shift away from the thorax, Ferek-Petric et al. apparently uses an intravascular impedance measurement of blood flow within a particular blood vessel. (See Ferek-Petric et al. at FIG. 1).

Similarly, Strandberg apparently also uses intravascular lead electrodes to measure impedance within a particular blood vessel to measure blood flow within that vessel. (See Strandberg at FIG. 5.) Although Combs et al. apparently measures thoracic impedance across a more substantial portion of the thorax that would include multiple blood vessels, as discussed above, it does not indicate a condition correlative to hypotension upon detection of a net fluid shift away from the thorax. Instead, as discussed above, Combs et al. measures pulmonary edema, that is, a fluid accumulation in the thorax, and therefore teaches away from the language recited or incorporated in claims 1, 3-8, 10, and 13. Because all elements of these claims are not present in Ferek-Petric et al. and/or Strandberg and/or Combs et al., Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Concerning claims 17, 19-25 and 27:

Applicant has amended claim 17, consistent with the above-discussed amendment to claim 1, to overcome this rejection of claim 17 and its dependent claims. For the reasons discussed above with respect to claim 1, Applicant respectfully submits that all elements of these claims are not present in Ferek-Petric et al. and/or Strandberg and/or Combs et al. and, therefore, no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

3. Claims 9, 11, 12, 14-16, 26 and 28-30 were rejected under 35 U.S.C. § 103(a) for obviousness over Ferek-Petric et al. (U.S. Patent No. 5,913,879) in view of Strandberg (EP 0 620 420 A1) and further in view of Combs et al. (U.S. Patent No. 5,957,861) and further in view of Sheldon et al. (U.S. Patent No. 6,044,297). Applicant respectfully traverses.

Because claims 9, 11, 12, and 14-16 incorporate all the language of independent claim 1, and claims 26 and 28-30 incorporate all the language of independent claim 17, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims for the same reasons discussed above with respect to claims 1 and 17.

Concerning claims 9 and 26:

Applicant can find no disclosure, teaching, or suggestion in the cited portions of Ferek-Petric et al. and/or Strandberg and/or Combs et al. of indicating hypotension when a substantially

instantaneous component of activity exceeds a long term component of patient activity, as recited in claim 9. Although Sheldon et al. apparently does disclose adjusting pacing rate based on patient activity, the cited portion of Sheldon et al. that mentions hypotension uses a change in posture (rather than a change in patient activity) to increase the pacing rate from 50 pulses per minute to 70 pulses per minute when the patient stands up (rather than to change a rate response factor, as discussed above). (See Sheldon et al. at column 7, lines 23 – 36.) By contrast, claim 9 would indicate hypotension upon a change in patient activity even without any accompanying change in posture, for example. Because all elements of claim 9 are not present in Ferek-Petric et al. and/or Strandberg and/or Combs et al., Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to this claim. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Concerning claim 11:

Applicant can find no disclosure, teaching, or suggestion in the cited portions of Ferek-Petric et al. and/or Strandberg and/or Combs et al. of detecting both a postural and non-postural hypotension. For example, Sheldon et al. responds to posture, rather than a change in patient activity from resting to active. By contrast, claim 11 would indicate hypotension regardless of whether the patient's posture has changed, for example. Because all elements of claim 11 are not present in Ferek-Petric et al. and/or Strandberg and/or Combs et al., Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to this claim. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Concerning claims 14 – 16 and 28 - 30:

Applicant can find no disclosure, teaching, or suggestion in the cited portions of Ferek-Petric et al. and/or Strandberg and/or Combs et al. of adjusting a rate-response factor. The Office Action states:

As to the rate responsive factor (claims 14-16 and 27-30), the rate responsive factor is stepped (col. 7 @ 31 – 34; col. 11 @ 63 – col. 12 @ 9) US 5354317 to Alt, incorporated by reference (col. 2 @ 51-53; col. 3 @ 7 – 17), discloses variable rate pacing to provide electrical output signals uniquely responsive to pre-selected positions, including gradual rate changes (Alt – abstract) to provide optimal pacing therapy for the subject's specific needs.

(Office Action at 8.) Applicant respectfully traverses. Applicant notes that, by their dependence on claim 1, claims 14 - 16 incorporate language that specifically defines what is meant by a “rate response factor.”

Claim 1 expressly defines the “rate response factor” as “relating: (a) a pacing rate at which stimulations are delivered to the subject’s heart; to (b) a respiration and sensor signal that is correlative to the subject’s metabolic need for cardiac output.” For example, in FIG. 3 of the present patent application, the “rate response factor” is a slope of the function mapping the activity or respiration sensor signal to the sensor-indicated pacing rate. Sheldon et al. does not disclose adjusting such a slope or other “rate response factor” relating a component of a patient activity or respiration metabolic need sensor signal to a sensor-indicated pacing rate. Instead, Sheldon et al. apparently merely steps up pacing from 50, when a patient is sitting, to 70 when the patient stands up. (*See* Sheldon et al. at column 7, lines 23 – 26.) Therefore, Sheldon et al. merely adjusts a “rate” rather than a “rate response factor.” Applicant respectfully submits that the term “rate response factor,” is expressly defined in the claims to have a meaning that is different from any reading as merely a “rate.”

The Office Action also relies on Alt (U.S. Patent No. 5,354,317) for this rejection. Like Sheldon et al., Alt is responsive to position, rather than to patient activity or respiration. As Alt explains:

In circumstances where the old position is a supine, reclining or prone position and the new position is standing, the rate control is effected to cause a transition from the old rate (for lying or seated reclining position) to the new rate (for the standing position) by first abruptly increasing the rate to a magnitude substantially exceeding the desired new rate, then gradually reducing the magnitude to the new rate. In other position changes, a smooth transition is effected between the old and new rates.

(Alt at Abstract.) Unlike the present claims, both Sheldon et al. and Alt will not detect and respond to hypotension resulting from a change in patient activity or respiration that does not correspond to a change in position. Like Sheldon et al., Alt apparently merely adjusts a “rate,” rather than adjusting a “rate response factor” within the meaning expressly defined within the present claims. Because the references fail to disclose, teach, or suggest adjusting a “rate response factor,” the particular adjustments to the “rate response factor” that are recited in claims

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 09/879665

Filing Date: June 12, 2001

Title: CARDIAC RHYTHM MANAGEMENT SYSTEM ADJUSTING RATE RESPONSE FACTOR FOR TREATING
HYPOTENSION

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14 – 16 and 28 – 30 are also absent from the cited references. Because all elements of claim 11 are not present in Ferek-Petric et al. and/or Strandberg and/or Combs et al., Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to this claim. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Serial Number: 09/879665

Dkt: 279.358US1

Filing Date: June 12, 2001

Title: CARDIAC RHYTHM MANAGEMENT SYSTEM ADJUSTING RATE RESPONSE FACTOR FOR TREATING
HYPOTENSIONCONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney 612-373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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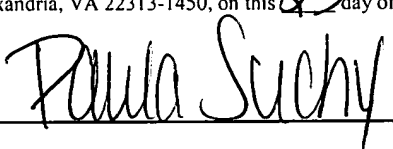
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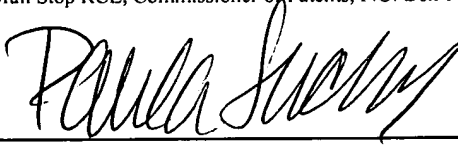

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23 day of January, 2004.



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